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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/923,132	08/06/2001	Gary S. Saylor	6704-15-1	8944
43463	7590	11/05/2004	EXAMINER	
RUDEN, MCCLOSKEY, SMITH, SCHUSTER & RUSSELL, P.A. 222 LAKEVIEW AVE SUITE 800 WEST PALM BEACH, FL 33401-6112			LAMBERTSON, DAVID A	
			ART UNIT	PAPER NUMBER
			1636	

DATE MAILED: 11/05/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/923,132

Applicant(s)

SAYLER ET AL.

Examiner

David A. Lambertson

Art Unit

1636

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 August 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3,5,8-12,16,18,19,23,25,27 and 29-48 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1-3,5,8-12,16,18,19,23,25 and 27 is/are allowed.
- 6) ☒ Claim(s) 29-48 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

Art Unit: 1636

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on February 19, 2004 has been entered.

Claims 1-3, 5, 8-12, 16, 18, 19, 23, 25, 27 and 29-48 are pending and under consideration in the instant application. Any rejection of record in the previous Office Action, mailed April 16, 2004, that is not addressed in this action has been withdrawn.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 29-48 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicant claims a device enclosed in water-tight packaging, wherein the device comprises a bacteria that is "capable of producing a detectable signal in response to an analyte."

Art Unit: 1636

By definition, an “analyte” is any composition that can be analyzed, which essentially reads on any composition. The specification teaches that placing an upstream response element (i.e., a nucleic acid comprising a promoter and/or operator element) in front of a reporter gene (e.g., the *lux* genes), confers upon the bacterium the ability to respond to an analyte by producing a detectable signal (i.e., the reporter gene). In this sense, the key element of the invention is the nature of the upstream response element, and its relationship to specific analytes. The claims read on a broad genus of devices comprising a broad genus of bacteria, wherein a given bacteria must comprise an upstream response element to any one of millions of analytes. Thus, the skilled artisan must be able to envision a corresponding response element for every analyte that needs to be detected in order to envision the claimed device (and method of using it).

The written description requirement for a claimed genus may be satisfied through sufficient description of a representative number of species by actual reduction to practice or by disclosure of relevant identifying characteristics, i.e. structure or other physical and/or chemical properties, by functional characteristics coupled with a known or disclosed correlation between function and structure, or by a combination of such identifying characteristics sufficient to show applicants were in possession of the claimed genus. In the instant case, the specification does not sufficiently describe a representative number of species by actual reduction to practice or by disclosure of relevant identifying characteristics.

Applicant claims a device comprising a bacterium capable of producing a detectable signal in response to an analyte by function only, without any disclosed or known correlation between the elements and their function. In other words, the claims read on a bacterium that can be engineered to respond to any desired analyte (i.e., the function) without disclosing which

Art Unit: 1636

response elements can be used to detect a given analyte (the structural element responsible for the function). The specification provides teachings concerning the detection of mercury as an analyte by engineering a promoterless *lux* reporter gene to be operably linked to a mercury responsive promoter element (such as *mer Ro/p*); in this instance, Applicant has shown that a given response element has the ability to respond to a particular analyte, thereby producing a detectable signal in the reporter gene. However, the specification does not teach that the mercury response element is capable of responding to virtually any analyte to produce a detectable signal, nor does the specification teach what response elements (i.e., structures) can elicit the required function of producing a detectable signal in the presence of any analyte. For example, the specification does not teach what response elements (i.e., structures) can be used to detect chemicals such as the carcinogens carbon tetrachloride, teleocidin, anthralin, or hundreds of other toxic chemicals that could be present in water samples. Thus, the skilled artisan cannot envision the broad genus of devices as claimed because the bacteria comprising appropriate response elements are not disclosed in the specification either explicitly, or through a structure-function relationship such that one of skill in the art would know which response elements can necessarily detect a given analyte.

The state of the art at the time of filing does not provide sufficient information on the subject to overcome the deficiencies of the instant specification. There is no description in the art that allows one to envision either a singular or plurality of different response elements to detect every known chemical/analyte. It is reiterated that the mercury response element that was originally elected is not capable of detecting the presence of every analyte, therefore it does not present a structure-function relationship for all such response elements. Similarly, response

Art Unit: 1636

elements that could be used to detect a great number of harmful compounds, such as carbon tetrachloride or teleocidin, were not known in the art at the time of filing. As a result, the skilled artisan could not envision the broad genus of bacteria comprising the necessary response elements to be used in the claimed device, making it impossible to envision the broad genus of devices that are claimed as a result.

Based on the teachings of the specification and the art at the time of filing, the ordinary skilled artisan would be unable to envision a broad genus of encapsulated bacteria that would be capable of producing a detectable signal in response to virtually any chemical compound. This is because the skilled artisan cannot envision the particular response elements that would be capable of directing the expression of a reporter gene (as taught for the mercury response element) in the presence of any particular analyte. As a result of the inability to envision the bacteria to be used in the claimed device (and method of using said device), the ordinary skilled artisan would not be able to envision the claimed device. Thus, the written description requirement has not been met for the claimed invention.

Claims 29-48 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a device enclosed in a water-tight packaging, wherein the device comprises an encapsulated bacteria capable of producing a detectable signal in response to mercury, does not reasonably provide enablement for a device enclosed in a water-tight packaging, wherein the device comprises an encapsulated bacteria capable of producing a detectable signal in response to any analyte. The specification does not enable any person skilled

Art Unit: 1636

in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The test of enablement is whether one skilled in the art could make and use the claimed invention from the disclosures in the specification coupled with information known in the art without undue experimentation (*United States v. Telectronics*, 8 USPQ2d 1217 (Fed. Cir. 1988)). Whether undue experimentation is needed is not based upon a single factor but rather is a conclusion reached by weighing many factors. These factors were outlined in *Ex parte Forman*, 230 USPQ 546 (Bd. Pat. App. & Inter. 1986) and again in *In re Wands*, 8 USPQ2d 1400 (Fed. Cir. 1988), and the most relevant factors are indicated below:

Nature of the invention. The nature of the invention is a device comprising a bacterium that has the ability to produce a detectable signal in response to an analyte. By definition, an analyte is any molecule, compound or composition that can be analyzed, and includes millions of chemicals. Thus, in order to practice the claimed invention across the broad scope in which it is claimed, the ordinary skilled artisan would need to be able to produce a bacterium that can detectably respond to any of these chemicals. In the instant specification, the detectable signal is generated by the activation of a promoter element (which has been operably linked to a reporter protein, such as a luciferase) that is responsive to an analyte (specifically exemplified by the use of the mer Ro/p, and its ability to respond to mercury). Based on the teachings of the specification, the skilled artisan would therefore need to know which promoter elements were capable of responding to every given analyte/chemical in order to make the broad scope of bacteria required to produce a detectable signal in response to a said analyte/chemical, and therefore to be able to use the claimed invention.

Art Unit: 1636

Breadth of the claims. The claims are extremely broad, requiring the ability to produce a bacterium that can detect any chemical that exists. Based on the teachings of the specification, this entails knowing the identity of a large number of promoter elements, and which of these elements has the ability to respond to a given chemical.

State of the art. The state of the art provides knowledge on only a few promoter elements that have the ability to respond to a particular analyte, and therefore that have the ability to produce a detectable signal in the presence of said analyte. These promoters include the mer Ro/p element exemplified in the instant specification as capable of producing a detectable signal in the presence of mercury. It is important to note that these other promoters have a structure-function relationship (between the promoter element and the analyte it detects) that is distinct from that of the mer Ro/p element; this is obvious from the fact that the mer Ro/p element does not produce a detectable signal in the presence of naphthalene, benzene, etc. As such, the skilled artisan cannot extrapolate from the knowledge in the art of these few promoters to attain the broad scope of promoter elements capable of producing a detectable signal in the presence of any of millions of chemicals. Indeed, it is entirely possible that a large number of analytes have no responsive promoter element, thus a bacterium that can produce a detectable signal in the presence of said analyte may be impossible to make.

Without the ability to envision these promoters and what particular analytes they can detect, the skilled artisan cannot make the bacteria to be used in the invention based on the teachings in the art at the time of filing. For example, the skilled artisan cannot make a bacterium that is capable of detecting the presence of carbon tetrachloride or teleocidin because it is unknown which (if any) promoter element can produce a detectable signal in response to

Art Unit: 1636

these carcinogenic compounds. The same statement can be made concerning a vast number of analytes that can allegedly be detected by the instant invention. Without the ability to make this key element in Applicant's invention (based on the fact that it is the operable portion of the claimed device), the skilled artisan would need to consult the instant specification on what promoter elements can be incorporated into a bacterium in order to produce a detectable signal in the presence of each given analyte.

Number of working examples and Guidance provided by applicant. The instant specification does not remedy the deficiencies of the teachings of the prior art as it regards the breadth of the claimed invention. The instant specification does not identify promoters that are not described in the art, and their ability to detect any given analyte. For instance, as indicated above, there is no description of a promoter element that can produce a detectable signal in response to carbon tetrachloride or teleocidin in a water sample. Thus, based upon the teachings of the instant specification, the ordinary skilled artisan could not make the bacterium to be used in the claimed device, or method of using said device.

Unpredictability of the art and Amount of experimentation required. The claimed invention is highly unpredictable and requires a vast amount of empirical experimentation in order to make and use the invention across the broad scope indicated. First, the skilled artisan would have to associate each of millions of analytes to a given promoter. This requires the skilled artisan to experimentally determine which known promoters are capable of responding in the presence of each individual analyte out of literally millions of analytes. It also requires the skilled artisan to experimentally identify promoters capable of responding to the analytes that do not elicit a response from known promoters, with the added caveat that there may be no such promoter.

Art Unit: 1636

This is highly unpredictable (especially given that many analytes may remain undetectable in terms of the claimed invention), and requires an undue amount of experimentation from the skilled artisan who must essentially determine the vast number of embodiments of the claimed invention. Because the skilled artisan would be reduced to performing an inventive step in order to make and use the claimed invention (i.e., identifying and/or characterizing any one of a number of promoters for the ability to produce a detectable signal in the presence of any one of millions of analytes), the invention lacks enablement across the broad scope in which it is claimed.

Allowable Subject Matter

Claims 1-3, 5, 8-12, 16, 18, 19, 23, 25 and 27 are allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David A. Lambertson whose telephone number is (571) 272-0771. The examiner can normally be reached on 6:30am to 4pm, Mon.-Fri., first Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel, Ph.D. can be reached on (571) 272-0781. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Art Unit: 1636

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


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AU 1636